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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,018	11/03/2003	Paul M. Lizardi	25006.0003U4	4956

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EXAMINER

TUNG, JOYCE

ART UNIT PAPER NUMBER

1637

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/700,018

Applicant(s)

LIZARDI, PAUL M.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32,34-44 and 46-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32 and 35-38 is/are allowed.
- 6) ☒ Claim(s) 34, 39-44, 46-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The applicant's response filed 8/28/06 to the Office action has been entered. Claims 32, 34-44, and 46-50 are pending.

1. The rejection of claims 34, and 39-45 under 35 U.S.C. 102(b) as being anticipated by Hartley (5,043,272, issued August 27, 1991) is withdrawn because of the amendment.
2. The rejection of claim 46 under 35 U.S.C. 103(a) as being unpatentable over Hartley (5,043,272, issued August 27, 1991) as applied to claims 34 and 39-45 further in view of Blanco et al. (Journal of Biological Chemistry, 1989, Vol. 264(15), pg. 8935-40) is withdrawn because of the amendment.
3. Claims 47-49 remain rejected under 35 U.S.C. 102(e) as being anticipated by McCaslin et al. (5,614,390, issued March 25, 1997).

McCaslin et al. disclose a kit to amplify a target nucleic acid using SDA (column 16, claim 23). The strand displacement DNA polymerase is Bst polymerase (See column 9, lines 14-15). The set of primers has 3 or more primers (See column 4, lines 49-67 and column 5, lines 1-20). Thus, the teachings of McCaslin et al. anticipate the limitations of the claims.

The response argues that McCaslin et al. do not disclose that all primers in the set of primers are complementary to the same strand of the target sequence, wherein the set of primers has 3 or more primers. However, it is unclear what is meant by the same strand of the target sequence. Does it include the complementary strand of the target sequence? Moreover, what is the definition regarding a set of primers. Since McCaslin et al. disclose the primer set which is consisted of target binding sequences of three upstream amplification primers and two downstream amplification primers (See column 4, lines 56-67, Table 1 and column 5, lines 1-

10), the teachings of McCaslin et al. anticipate the limitations of the claims. Thus, the rejection is maintained.

4. Claim 47 is rejected under 35 U.S.C. 102(e) as being anticipated by Walker et al. (5,736,365, issued April 7, 1998).

Walker et al. disclose a kit used to pack the primer or the probes for performing the assay (See column 10, lines 54-57). The primer set has 3 or more primers (an amplification primer, an adapter primer and an bumper primer) (See column 4, lines 48-67, column 5, lines 18). The polymerase has a strand displacement factor (See column 11, lines 29-30). Thus, the teachings of Walker et al. anticipate the limitations of the claims.

The response argues that Walker et al. do not disclose that all of the primers in the set of primers are complementary to the same strand of the target sequence, wherein the set of primers has 3 or more primers. As discussed in section 3 above, it is unclear what is meant by the same strand of the target sequence. Does it include the complementary strand of the target sequence? Moreover, what is the definition regarding a set of primers in which the primers are complementary to the target sequence and complementary to the complementary sequence of the target sequence. Walker et al. disclose an amplification primer, an adapter primer and bumper primer in which all of the primers are complementary to the target sequence (See column 4, lines 48-67, column 5, lines 18). Thus the teachings of Walker et al. anticipate the limitations of the claims and the rejection is maintained.

5. Claim 50 remains rejected under 35 U.S.C. 103(a) as being unpatentable over McCaslin et al. (5,614,390, issued March 25, 1997) as applied to claims 47-49 or over Walker et al.

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(5,736,365, issued April 7, 1998) as applied to claim 47 above, and further in view of Blanco et al. (Journal of Biological Chemistry, 1989, Vol. 264(15), pg. 8935-40).

None of the references above discloses that the kit contains phage vphi 29 DNA polymerase for strand displacement.

Blanco et al. disclose that phage vphi 29 DNA polymerase is highly processive in the absence of any accessory protein and is able to produce strand displacement coupled to the polymerization process (See the Abstract).

One of ordinary skill in the art would have been motivated to include phage vphi 29 DNA polymerase in the kit for amplifying a target nucleic acid as claimed because of the benefit of using the polymerase. It would have been prima facie obvious to include phage vphi 29 DNA polymerase in the kit for performing the amplification of the target nucleic acid.

The response has the same argument as to the rejection of claims 47-49. With the same reasons as set forth in sections 3-4 above, the rejection is maintained.

6. Claims 32 and 35-38 remain allowed.

7. The following is a statement of reasons for the indication of allowable subject matter:

Concerning claims 32 and 35-38, no prior art has been found teaching or suggesting the kit comprising a set of primers wherein the set of primers comprises a right set of primers and a left set of primers, wherein the right set of primers has 4 or more primers and the left set of primers has 4 or more primers, wherein the right set of primers is all complementary to the first strand of a target sequence and each complementary to a different portion of the right hybridization target of the first strand of the target sequence and the left set of primers is all

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complementary to the second strand of the target sequence and each complementary to a different portion of the left hybridization target of the second strand of the target sequence.

The closest prior art is the reference of Walker et al. (5,736,365, issued April 7, 1998). Walker et al. disclose a kit used to pack the primer or the probes for performing the assay (See column 10, lines 54-57). The primer set has 3 or more primers (an amplification primer, an adapter primer and an bumper primer) on a right hybridization target and a left hybridization target (See column 4, lines 48-67, column 5, lines 18). Walker et al. do not disclose that the set of primers has a right set of primers and a left set of primers, wherein the right set of primers has 4 or more primers and the left set of primers has 4 or more primers.

NEW GROUND OF REJECTION

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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9. Claims 34 and 39-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Hartley (5,043,272, issued August 27, 1991) in view of Van Gelder et al. (5,891,636, issued April. 6, 1999).

Hartley et al. disclose a kit for amplifying a nucleic acid sequence including primers having random nucleotide sequences and polymerase possessing strand displacement activity (see column 4, lines 43-68 and column 8, lines 35-36). The sample is from human or other animal source (See column 3, lines 6-21). The primer is 5-50 bases fragment (See column 6, lines 59-62). Thus, the teachings of Hartley et al. anticipate the limitations of the claims.

Hartley et al. do not disclose the random primer comprising a constant portion.

Van Gelder et al. disclose the use of promoters for ribonucleic acid amplification and other genetic manipulations (See the Abstract). The invention can be provided in kit form for a variety of uses (See column 3, lines 43-44). The kit may contain random primers linked to a promoter reactive with the RNA polymerase (See column 10, lines 46-57). The promoter region has constant portion which has the same nucleotide sequence (See column 4, lines 62-65).

One of ordinary skill in the art would have been motivated to include the random primer comprising a constant portion having the same nucleotide sequence as disclosed by Van Gelder et al. in the kit for amplifying a target nucleic acid sequence because as indicated by Van Gelder et al. the kit containing the random primer with the portion having the same nucleotide sequence can have a variety of uses (See column 3, lines 43-44). It would have been prima facie obvious to include the random primer with the portion having the same nucleotide sequence in the kit for amplifying a target nucleic acid sequence.

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10. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley (5,043,272, issued August 27, 1991) in view of Van Gelder et al. (5,891,636, issued April. 6, 1999) as applied to claims 34 and 39-44 and further in view of Blanco et al. (Journal of Biological Chemistry, 1989, Vol. 264(15), pg. 8935-40).

None of the references above discloses that the kit contains phage vphi 29 DNA polymerase for strand displacement.

Blanco et al. disclose that phage vphi 29 DNA polymerase is highly processive in the absence of any accessory protein and is able to produce strand displacement coupled to the polymerization process (See the Abstract).

One of ordinary skill in the art would have been motivated to include phage vphi 29 DNA polymerase in the kit for amplifying a target nucleic acid as claimed because of the benefit of using the polymerase. It would have been prima facie obvious to include phage vphi 29 DNA polymerase in the kit for performing the amplification of the target nucleic acid.

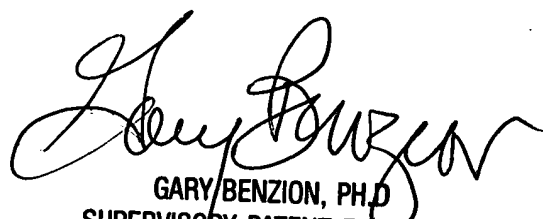
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joyce Tung
November 1, 2006


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